II. REMARKS

A. Introduction

Applicants submit this Response in a bona fide attempt to (i) advance the prosecution of this case, (ii) answer each and every ground of objection and rejection as set forth by the Examiner, (iii) place the claims in a condition for allowance, and (iv) place the case in better condition for consideration on appeal. Applicants respectfully request reexamination and reconsideration of the above referenced patent application in view of this Response.

As indicated above, Claims 1 - 12 have been amended. New Claims 13 – 17 have also been added.

Applicants respectfully submit that the noted amendments merely make explicit that which was (and is) disclosed or implicit in the original disclosure. The amendments thus add nothing that would not be reasonably apparent to a person of ordinary skill in the art to which the invention pertains.

B. Response to Objections

The Examiner has rejected Claim 12 under 37 CFR 1.75(c) "as being of improper dependent form for failing to further limit the subject matter of a previous claim." Applicants have accordingly amended Claim 12 to change the dependency of Claim 12 from Claim 5 to Claim 6.

C. Response to Rejections

1. Double Patenting

The Examiner has rejected Claims 1 – 12 under the judicially created doctrine of obviousness-type double patenting "as being unpatentable over claims 1 – 10 of U.S. Patent No. 6,681,136." The Examiner contends:

> Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims meet the limitations of the applications claims except for delivering it to a blood pressure regulatory point.

The Examiner has also rejected Claims 1 – 12 under the judicially created doctrine of obviousness-type double patenting "as being unpatentable over claims 1 – 12 of Co-Pending Application No. 10/781,078." The Examiner similarly contends:

> Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims meet the limitations of the applications claims except for delivering it to a blood pressure regulatory point.

Applicants are accordingly submitting herewith a Terminal Disclaimer to overcome each of the double-patenting rejections.

2. 35 U.S.C. § 101

The Examiner has rejected Claims 6 and 12 under 35 U.S.C. § 101. The Examiner contends that "the claimed invention is directed to non-statutory subject matter."

> Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders [claims 6 and 12] non-statutory.

Applicants have accordingly amended Claim 6 to reflect that the treatment member "is adapted to be in communication with the body." Claim 12 has also been amended to reflect that the treatment member "is adapted to be implanted in the body."

3. 35 U.S.C. § 112

The Examiner has rejected Claims 7 – 11 under 35 U.S.C. § 112, second paragraph, "as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

Applicants have accordingly amended Claims 7 – 11 to change the dependency of the noted claims from Claim 5 to Claim 6, as recommended by the Examiner.

4. 35 U.S.C. § 102

The Examiner has rejected Claims 1-6 and 9-12 "under 35 U.S.C. § 102(e) as being anticipated by... Kieval et al (US 6,522,926)." The Examiner contends, *inter alia*:

> Kieval et al. discloses a device to "be used to increase or decrease blood pressure, sympathetic nervous system activity and neurohormonal activity, as needed to minimize deleterious effects on the heart, vasculature and other organs and tissues" (col 21, lines 11-14) by activating the baroreceptors. Kieval et al also discloses in column 21, lines 15-16 that "the baroreceptor activation devices described previously may be used to provide antiarrhythmic effects". As seen in figure 3, "the control system 60 generates a control signal as a function of the received sensor signal.

It is well established that a rejection for anticipation under § 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. *See In re Paulsen,* 30 F.3d 1475, 1478-79, 31 U.S.P.Q. 2d 1671, 1673 (Fed. Cir. 1994); *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 U.S.P.Q. 2d 1001 (Fed. Cir.1991). *See also American Permahedge, Inc. v. Barcana, Inc.*, 857 F. Supp. 308, 32 U.S.P.Q. 2d 1801, 1807-08 (S.D. NY 1994) ("Prior art anticipates an invention ... if a single prior art reference contains each and every element of the patent at issue, operating in the same fashion to perform the identical function as the patent product. ... Thus, any degree of physical difference between the patented product and the prior art, *no matter how slight,* defeats the claim of anticipation."); *Transco Ex parte Levy*, 17 U.S.P.Q. 2d 1461, 1462 (Bd. Pat. App. & Int'l 1990) ("[I]t is incumbent upon the examiner to identify wherein each and every facet of the claimed invention is disclosed in the applied reference".)

Applicants respectfully submit that the claimed invention is ***not*** anticipated by Kieval et al. Indeed, as discussed in detail below, Kieval et al. simply does not disclose "each and every limitation of the claimed invention."

Independent Claim 1, as amended, includes the steps of (i) providing a plurality of waveform signals representative of waveform signals generated in the body and carried by neurons in the body, the plurality of waveform signals including first waveform signals operative in the control of cardiac function and (ii) broadcasting the first waveform signals from a treatment member "directly" to a cardiac regulatory point in the body.

The apparatus recited in independent Claim 6, as amended, includes (i) a source of collected waveform signals indicative of body organ functioning, the waveform signals including first waveform signals operative in the control of cardiac function and (ii) a treatment member adapted to broadcast the first waveform signals "directly" to a cardiac regulatory point in the body.

Applicants' waveform signals thus specifically include waveform signals that are similar to the waveforms or waveform signals that are naturally produced by the brain stem structures for modulating cardiac function. The type, form and function of the waveform signals transmitted to the blood pressure regulatory point are thus ***solely*** determined or dictated by the actual waveform signals generated in the body to modulate cardiac function.

Further, the waveform signals are broadcasted or transmitted "directly" to a cardiac regulatory point by the treatment member. The noted communication by and between the treatment member and cardiac regulatory point is thus achieved without an intermediate component or device.

In contrast, Kieval et al. discloses generating and transmitting "user determined" and "device determinative" control signals, which are ***not*** related to or representative of waveform signals generated in the body, to an intermediate component, i.e., a baroreceptor activation device, to effect a change in the baroreflex system.

> Generally speaking, the baroreceptor activation device may be activated, deactivated or otherwise modulated to activate one or more baroreceptors and induce a baroreceptor signal or a change in the baroreceptor signal to thereby effect a change in the baroreflex system. The baroreceptor activation device may be activated, deactivated, or otherwise modulated continuously, periodically, or episodically. The baroreceptor activation device may comprise a wide variety of devices which utilize mechanical, electrical, thermal, chemical, biological, or other means to activate the baroreceptor. The baroreceptor may be activated directly, or activated indirectly via the adjacent vascular tissue. The baroreceptor activation device may be positioned inside the vascular lumen (i.e., intravascularly), outside the vascular wall (i.e., extravascularly) or within the vascular wall (i.e., intramurally). (emphasis added) Col. 3, ll. 40-55

* * *

> The control signals generated by the control system 60 may be continuous, periodic, episodic or a combination thereof, as dictated by an algorithm contained in memory. Continuous control signals include a constant pulse, a continuous train of pulses, a triggered pulse and a triggered train of pulses. Examples of periodic control signals described above which have a designated start time (e.g., beginning of each minute, hour or day) and a designated duration (e.g., 1 second, 1 minute, 1 hour). Examples of episodic control signals include each of the continuous control signals described above which are triggered by an episode (e.g., activation by patient/physician, an increase in blood pressure above a certain threshold, etc. (emphasis added) Col. 9, ll. 52-65

Kieval et al. thus transmits "user determined and selected" and "device determinative" signals to a baroreceptor activation device. See, for example, Col. 10, ll. 58-63 (electrical signals to actuate a driver 66); Col. 11, ll. 41-61 (selective delivery of electrical power to a deformable structure device 140); Col 14, ll. 11-35 (selective actuation of a magnetic coil 224 to create a magnetic field, which, in turn, moves magnetic particles); Col. 16, ll. 35-38 (electrical control signals to activate an electrode structure 282). The Kieval et al. signals are thus substantially different in type, form and function from Applicants' waveform signals.

Kieval et al thus does not disclose "each and every limitation of the claimed invention." Applicants accordingly respectfully request that the rejection under 35 U.S.C. § 102 be withdrawn.

5. 35 U.S.C. § 103

The Examiner has alternatively rejected Claims 1-12 under 35 U.S.C. § 103(a) as being unpatentable over Kieval et al. The Examiner primarily contends that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the control system and method as taught by Kieval et al. with a memory to store waveforms since it was known in the art that storing and recording data can provide physicans with information on the status of a patient."

It is well established that in determining what is and what is not obvious under § 103, all properties and advantages not in the prior art must be considered. See *In re Wright*, 848 F.2d 1216, 6 U.S.P.Q. 2d 1959, 1962 (Fed. Cir. 1988) ("Factors including unexpected results, new features, solution of a different problem, novel properties, are all considerations in the

determination of obviousness in terms of 35 U.S.C. § 103"). Indeed, it is the invention as a whole, **including distinct functions** of the invention (including components or steps thereof), that must be considered in obviousness determinations.

It is further well established that a § 103 rejection based upon a modification of a reference that destroys the intent, purpose or function of the invention disclosed in the reference, is not proper and a prima facie case of obviousness cannot properly be asserted. In short, there would be "no technological motivation for engaging in the modification or change. To the contrary, there would be a disincentive. See *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

Applicants respectfully submit that Claims 1-12 define an invention that is unobvious over Kieval et al. As set forth above, Applicants' apparatus and method employ "waveform signals representative of waveform signals generated in the body and carried by neurons in the body." The noted waveform signals are stored and selectively transmitted ***directly*** to a cardiac regulatory point in the body.

Kieval et al. simply does not teach or suggest the direct transmission of waveform signals representative of waveform signals generated in the body and carried by neurons to modulate blood pressure. Kieval et al. merely teaches the use of "continuous control signals, periodic control signals, episodic control signals, or combinations thereof" that are specifically and solely tailored to activate a baroreceptor activation device, which, in turn, activates and/or controls baroreceptors. The control signals are thus "user determined", "device determinative" and ***not*** related to or representative of waveform signals generated in the body.

Applicants further submit that the asserted modification of Kieval et al.'s control system, i.e., storing and transmitting the waveform signals employed in Applicants' invention, would destroy the intent, purpose and function of the control system and baroreceptor activation device. Indeed, as set forth above, the signals employed in Kieval et al are "device determinative" and, hence, tailored to activate a selected baroreceptor activation device. The Kieval et al. system thus simply would not function if the waveform signals employed by Applicants were transmitted to the baroreceptor activation device.

Applicants thus submit the claimed invention should be deemed unobvious over Kieval et al. Claims 1 and 6, and all claims dependent thereon, should thus be deemed allowable.

Applicants have also reviewed the prior art made of record and not relied upon by the Examiner and have found them not to teach or make obvious the present invention.

III. CONCLUSION

Applicants having answered each and every ground of objection and rejection as set forth by the Examiner, and having added no new matter, believe that this response clearly overcomes the reference of record, and now submit that all claims in the above-referenced patent application are in condition for allowance and the same is respectfully solicited.

If the Examiner has any further questions or comments, Applicants invite the Examiner to contact their Attorneys of record at the telephone number below to expedite prosecution of the application.

Respectfully submitted,
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